

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Frank A. Skraly and Oliver P. Peoples

Serial No.: Continuation of 09/488,348 Art Unit: Not Yet Assigned

Filed: June 20, 2003 Examiner: Not Yet Assigned

For: *POLYHYDROXYALKANOATE BIOPOLYMER COMPOSITIONS*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including four (4) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/488,348, filed January 20, 2000, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
3,275,610	09-27-1966	Coty	260/80
4,477,654	10-16-1984	Holmes, et al.	528/361
5,534,432	07-09-1996	Peoples, et al.	435/240.4
5,798,235	08-25-1998	Peoples, et al.	435/135

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 99/14313	03-25-1999	Metabolix, Inc.	PCT

Publications

BRAUNEGG, et al., "Polyhydroxyalkanoates, biopolyesters from renewable resources: physiological and engineering aspects," Journal of Biotechnology 65:127-161 (1998).

CAO, et al., "Thermal and morphological study of fractionated poly(3-hydroxybutyric acid-co-3-hydroxypropionic acid," Macromol. Chem. Phys. 198:3539-3557 (1997).

CHOI & LEE, "Factors affecting the economics of polyhydroxyalkanoate production by bacterial fermentation," Appl. Microbiol. Biotechnol. 51:13-21 (1999).

DOI, "Microbial Synthesis, Physical Properties, and Biodegradability of Polyhydroxyalkanoates," Macromol. Symp. 98:585-599 (1995).

FUKUI, et al., "Purification and characterization of NADP-linked acetoacetyl-CoA reductase from Zoogloea ramigera I-16-M," Biochimica Et Biophysica Acta 917:365-371 (1987).

GERNGROSS, et al., "Overexpression and purification of the soluble polyhydroxyalkanoate synthase from Alcaligenes eutrophus: Evidence for a required posttranslational modification for catalytic activity," Biochemistry 33:9311-9320 (1994).

HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of Escherichia coli," FEMS Microbiol. Lett. 153:411-418 (1997).

HII & COURTRIGHT, "Induction of acyl coenzyme A synthetase and hydroxyacyl coenzyme A dehydrogenase during fatty acid degradation in Neurospora crassa," J. Bacteriol. 150(2):981-983 (1982).

HOFMEISTER & BUCKEL, "(R)-lactyl-CoA dehydratase from *Clostridium propionicum*. Stereochemistry of the dehydration of (R)-2-hydroxybutyryl-CoA to crotonyl-CoA," *Eur. J. Biochem.* 206(2):547-552 (1992).

JESUDASON & MARCHESSAULT, "Synthetic Poly[(R,S)-.beta.-hydroxyalkanoates] with Butyl and Hexyl Side Chains," *Macromolecules* 27:2595-602 (1994).

LEE, et al. *Appl. Microbiol. Biotechnol.* 42(6): 901-909 (1995).

LEE, et al., "Copolymerization of gamma-valerolactone and beta-butyrolactone," *Eur. Polym. J.* 34: 117-122 (1998).

MADISON & HUISMAN, "Metabolic engineering of poly(3-hydroxyalkanoates): from DNA to plastic," *Microbiology and Molecular Biology Reviews* 63:21-53 (1999).

NAWRATH, et al., "Targeting of the polyhydroxybutyrate biosynthetic pathway to the plastids of *Arabidopsis thaliana* results in high levels of polymer accumulation," *Proc. Natl. Acad. Sci. USA* 91:12760-64 (1994).

PEOPLES & SINSKEY, "Poly- β -hydroxybutyrate (PHB) biosynthesis in *Alcaligenes eutrophus* H16. Identification and characterization of the PHB polymerase gene (phbC)," *J. Biol. Chem.* 264:15298-15303 (1989).

PEOPLES, et al., "Biosynthetic Thiolase from *Zoogloea ramigera*," *J. Biol. Chem.* 262:97-102 (1987).

SAITO, et al., "An NADP-linked Acetoacetyl CoA reductase from *Zoogloea ramigera*," *Arch. Microbiol.* 114:211-217 (1977).

SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate)," *Polym. Int.* 39:169-174 (1996).

SAITO, et al., *Intl. J. Biol. Macromol.* 16(2): 99-104 (1994).

SENIOR & DAWES, "The regulation of Poly-.beta.-hydroxybutyrate Metabolism in *Azobacter beijerinckii*," *Biochem. J.* 134:225-228 (1973).

SHIMAMURA, et al., "Microbial Synthesis and Characterization of Poly(3-hydroxybutyrate-co-3-hydroxypropionate)," *Macromolecules* 27:4429-4435 (1994).

SÖHLING & GOTTSCHALK, "Molecular analysis of the anaerobic succinate degradation pathway in *Clostridium kluyveri*," *J. Bacteriol.* 178:871-880 (1996).

STEINBÜCHEL & GORENFLO, "Biosynthetic and biodegradable polyesters from renewable resources: current state and prospects," *Macromol. Symp.* 123:61-66 (1997).

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VALENTIN, et al., "Identification of 4-hydroxyvaleric acid as a constituent of biosynthetic polyhydroxyalkanoic acids from bacteria," Appl. Microbiol. Biotechnol. 36:507-14 (1992).

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WILLIAMS & PEOPLES, "Biodegradable plastics from plants," Chemtech 26:38-44 (1996).

YIM, et al., "Synthesis of Poly-(3-hydroxybutyrate-co-3-hydroxyvalerate) by recombinant *Escherichia coli*," Biotech. Bioengineering 49:495-503 (1996).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

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Reg. No. 48,731

Dated: June 20, 2003

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number

Continuation of 09/488,348

Filing Date

June 20, 2003

First Named Inventor

Frank A. Skraly

Group Art Unit

Examiner Name

Attorney Docket Number

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OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		BRAUNEGG, et al., "Polyhydroxyalkanoates, biopolyesters from renewable resources: physiological and engineering aspects," Journal of Biotechnology 65:127-161 (1998).	
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				First Named Inventor	
Frank A. Skraly					
Group Art Unit					
Examiner Name					
Attorney Docket Number					
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Sheet	3	of	4
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		LEE, et al. Appl. Microbiol. Biotechnol. 42(6): 901-909 (1995).	
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